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PRINCIPAL INVESTIGATOR: Isaac Lipkus, Ph.D.

CONTRACTING ORGANIZATION: Duke University
Durham NC 27710

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6. AUTHOR(S)
Isaac Lipkus, Ph.D.

E-Mail: lipku001@mc.duke.edu

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14. ABSTRACT
During this reporting period, the focus has been on continued recruitment and completing the laboratory and follow up surveys. No analyses have been performed during this period. No significant changes were made to study design or instruments. No adverse events or study deviations occurred. Two protocol deviations from prior years that were not previously reported are indicated here. Recruitment and study numbers are updated for the reporting period.

15. SUBJECT TERMS
tamoxifen, chemoprevention, breast, cancer, risk, communication.

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Table of Contents

I. Introduction

The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. The specific aims are to test how conveying (1) breast cancer risk as a frequency (e.g., 10 out of 10,000) or probability (e.g., .1%) affects perceived BC risks and negative emotions (e.g., fear, worry) about getting BC, the extent of processing information about Tamoxifen's risks and benefits (i.e., how much time is spent reviewing data on Tamoxifen), and intentions to use and talk to a health care provider about Tamoxifen use and (2) Tamoxifen's risks and benefits as frequencies or probabilities, individually and jointly interact with the BC risk format to affect women's weighing of the risks and benefits, intentions to use and talk with a health care provider about Tamoxifen use.

II. Body: <u>Accomplishments as Outlined in the Approved Statement of Work</u>

A. Task 1: Prepare Experimental and Recruitment Materials

No work in this section was done in the current reporting year. All tasks in this section were accomplished during prior years as summarized here: Development of all computer programs, preparation of risk communication formats and survey instruments, and pilot testing of recruitment methods, as outlined in the statement of work, were done in 2003/2004 and were reported in the 2004 progress report. Consent and the following questionnaires in order remain approved by the Duke University Medical Center Institutional Review Board (IRB): telephone screener, baseline, need for cognition, numeracy, BIS, EPrime (thoughts and feelings about breast cancer risk and tamoxifen), reaction to tamoxifen (percent and frequency versions), and 1 month follow up. Web based information for communicating information about cancer risks and tamoxifen risk and benefit also remains approved by the Duke University Medical Center Institutional Review Board (IRB). All research staff were hired and trained.

B. Task 2: Conduct Recruitment and Experimental Procedures

During the period since the 2005 progress report, no significant changes were made to study design or instruments. No adverse events or study deviations occurred during this period. We have applied for and were granted a no-cost extension until September 2007 to finish data collection and analysis.

Two deviations of protocol happened in years prior to this reporting period and were not included on annual summaries. They are outlined here:

- In November 2004, it was noted that research staff were inadvertently pulling all appointments from the gynecology schedule, which included appointments scheduled by the doctors for procedures such as mammograms, bone scans, etc. These participants were not actually seeing their GYN provider. We corrected this problem and submitted a deviation notification to the Duke University Medical

Center IRB and since that time are no longer getting participants unless they have a consultation scheduled with their provider. In the meantime, a few participants have entered the studies that had only a mammogram scheduled and were documented accordingly.

- In February 2005, it was noted that incorrect information was generated due to an internal error in the computer program that calculated risks for developing endometrial cancer, deep vein thrombosis, pulmonary embolism, cataracts, and stroke inaccurately. Rather than tailoring the risks based on age and race of the participant, all 21 participants were given the risks for a Caucasian female aged 35-39. Once the error was noted, a deviation notification to the Duke University Medical Center IRB, along with an amendment to recontact these participants with correct risk information. This computer program was also corrected and all subsequent participants have been given correct risk information for these five health states.

During this reporting period, the focus has been on continued recruitment and completing the laboratory and follow up surveys. Our original planned enrollment was 400 women. We are currently targeting recruitment for 250-300 women.

To date, there have been 3966 recruitment letters mailed. 2293 women have completed the screening, which equates to a 58% response rate. Of the 2293 women screened, there were 1972 ineligible (risk < 1.66%, prior diagnosis of breast cancer, DCIS, LCIS, prior clinical or research use of tamoxifen, or currently pregnant) and 321 women eligible for the study. Out of the 321 initially eligible women, 200 completed verbal consent and baseline survey (62%) beginning September 2004.

Among the 200 baseline surveys completed, 167 labs with written consent were completed; 84% of the labs have been completed. With approval from the Duke University Medical Center IRB, we pilot tested the surveys and administered and evaluation form on the first 10 eligible participants and were satisfied, based on the results of the evaluation, with proceeding with the study. Prior to the lab, 17 participants (9%) withdrew (did not wish to proceed with the study) and 12 (6%) were lost (met with their gynecologist and were thus no longer eligible to complete the lab). 4 participants are pending scheduling a laboratory appointment.

157 were eligible to complete the one-month follow up, beginning in December 2004. Of these, 135 (86%) have been completed. 2 (1%) withdrew and 5 (3%) were lost (call window expired at 3 months post laboratory visit) prior to 1 month follow up. The one-month follow-up is pending for 15 participants.

C. Conduct analyses of all data and submit main outcomes paper

No analyses have been done since the 2005 summary. No main analyses will be done until we have finished data collection.

III. Key Research Accomplishments

During this reporting period, no data was analyzed or presented. No main analyses will be done until we have finished data collection.

IV. Reportable Outcomes

No analyses have been done since the 2005 summary. No main analyses will be done until we have finished data collection.

V. Conclusions

None

VI. References

None